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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/813,326	03/30/2004	Per Gisle Djupesland	44508-058	5109
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PROSKAUER ROSE LLP PATENT DEPARTMENT 1585 BROADWAY NEW YORK, NY 10036-8299			EXAMINER MENDOZA, MICHAEL G	
			ART UNIT 3734	PAPER NUMBER
			MAIL DATE 12/27/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/813,326	<b>Applicant(s)</b> DJUPESLAND, PER GISLE	
	<b>Examiner</b> Michael G. Mendoza	<b>Art Unit</b> 3734	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 10 August 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-51 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4, 10, 19-39, 43, 44 and 47-51 is/are rejected.
- 7) ☒ Claim(s) 5-9, 11-18, 40-42, 45 and 46 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Response to Arguments***

1. Applicant's arguments, see arguments pages 8 and 9, filed 10 August 2007, with respect to the rejection(s) of claim(s) 1-3, 10, 21-23, 26-29, 36, 37, and 47-51 under 35 USC 102(b) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Harding 419942.

2. Applicant's request for reconsideration of the finality of the rejection of the last Office action is persuasive and, therefore, the finality of that action is withdrawn.

### ***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1, 2, 10, 21-23, 26-29, 36-39, and 47-51 are rejected under 35 U.S.C. 102(b) as being anticipated by Harding 419942.

5. Harding teaches a method of delivering a substance to the nasal airway of a subject, comprising the steps of: sealing one the nostrils of a subject to an outlet of a delivery unit such as to prevent the escape of gas flow through the one nostril (lines 49-54); and delivering a gas flow entraining a substance through the outlet at a driving pressure (lines 67-73). It is inherent that when one breathes through the mouth the oropharyngeal velum is closed. It would be inherent that if one nostril is sealed and is

receiving gas flow, and the oropharyngeal velum is closed, that the only way for the gas flow to escape is around the posterior margin of the nasal septum and out of the other nostril of the subject as evidenced by Grossan. Grossan describes the flow of fluid through one nostril and out the other when one nostril is sealed to an outlet dispensing a fluid (see abstract lines 25-30). Harding teaches the method of claim 1, wherein the velum closure step is provided by exhalation by the subject; wherein the gas flow entraining a substance is provided by the exhalation flow of the subject; wherein the substance comprises a dry powder; wherein the substance contains a medicament, particularly for the treatment of a nasal condition; and delivering a substance to the posterior region of the nasal airway.

6. As to claims 22, 23, 27, 28, 36, 37, 47-51, it has been held that to be entitled to weight in method claims, the recited structure limitations must affect the method in a manipulative sense, and not to amount to the mere claiming of a use of a particular structure. *Ex parte Pfeiffer*, 1962 C.D. 408 (1961).

***Claim Rejections - 35 USC § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 24, 25, and 30-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Harding.

9. As to claims 24 and 25, Harding discloses the claimed invention except for a particle size distribution in the range of about 1 to 10  $\mu\text{m}$ . It would have been obvious to one having ordinary skill in the art at the time the invention was made to use the claimed range, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, USPQ 233.

10. Harding teaches a device for dispensing an agent through the nostril of a subject. Any type of agent can be used within the devices depending on the ailment of the subject. The device of Harding can be used to treat nasal ailments including the limitations of the claims 30-35.

11. Claims 3 and 4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Harding in view of Keldmann et al. WO 98/53869.

12. As to claim 3, Harding teaches the method of claim 2. It should be noted that Harding fails to teach wherein the exhalation is through a flow resistor. However, Keldmann teaches a similar device using a similar method using a resistor. Therefore, it would have been obvious to one having ordinary skill in the art to include the step of using a resistor in the method as taught by Harding to increase the delivery efficiency of a medicament (pg. 3, lines 9-23).

13. As to claim 4, Harding/Keldmann fails to specifically teach wherein the flow resistor is configured to maintain a positive pressure differential of at least about 5 cm  $\text{H}_2\text{O}$ . However, Harding/Keldmann is fully capable of meeting the recited limitations.

Keldmann et al. teaches an adjustable resistor that can be adjusted to the claim limitations (pg. 3, lines 9-23).

14. Claims 19 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Harding in view of Butler et al. 5937852.

15. Harding teaches the delivery device of 1. It should be noted that Harding fails to teach the delivery unit further comprising an indicator.

Butler et al. teaches a delivery device with a common indicator as visual stimulus. Therefore it would have been obvious to one of ordinary skill in the art to modify the device of Harding to include the indicator of Butler et al. to indicate when the user is actually exhaling (col. 2, line 67 – col. 3, line 1).

***Allowable Subject Matter***

16. Claims 5-9, 11-18, 40-42, 45, and 46 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael G. Mendoza whose telephone number is (571) 272-4698. The examiner can normally be reached on Mon.-Fri. 9:00 a.m. - 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hayes can be reached on (571) 272-4959. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



MM



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